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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,203	01/29/2001	Sharron Gaynor Penn	AEOMICA-1	7320

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EXAMINER	
CLOW, LORI A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/774,203	PENN ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp nd nce address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-81 and 93-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-81 and 93-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper[redacted](s) See below
6/29/2001; 7/9/2001; 8/21/2001; 5/7/2002; 8/6/2002
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of Group XI in the response dated 10 November 2003 is acknowledged.

Claims 61-81 and 93-104 are currently pending.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See for example pages 33 and 65.

Information Disclosure Statement

The Information Disclosure Statements, filed 9 July 2001, 21 August 2001, and 6 August 2002 have been entered and considered. Initialed copies of the PTO-1449 forms are included with this office action. The Information Disclosure Statement submitted 29 June 2001 has been partially considered. Reference 11, page 3 has been lined through and not considered, as it does not contain a date. Reference 5, page 4 is missing from the submitted papers and has not been considered. The Information Disclosure Statement submitted 7 May 2002 has been partially considered. Reference 7 is missing from the submitted papers and has not been considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 61-81 and 93-104 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims recite an array comprising a plurality of nucleic acid probes wherein the probes include genomic sequences predicted to contribute to no more than on exon of a eukaryotic genome. The specification teaches that the arrays of the instant invention would be useful for monitoring gene expression and identifying functional genes from genomic data. However, these utilities lack specific and substantial utility for the claimed set of nucleic acid arrays.

The seminal decision interpreting the utility requirement of § 101 is Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). See MPEP 2107.

These utilities are not specific for the claimed nucleic acid array because they are utilities that could be ascribed to any nucleic acid array with fragments of genomic DNA from open reading frames of a eukaryotic genome.

In the decision Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), the Court noted that although § 101 requires that an invention be "useful," that "simple, everyday word can pregnant with ambiguity when applied to the facts of life." Id. at 529, USPQ at 693. Thus,

> [it] is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the "new and useful" phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man's grasp and where little or nothing is wholly beyond the pale of "utility"-if that word is given its broadest reach.

Id. at 530, 148 USPQ at 694.

Brenner's standard has been interpreted to mean that "vague, general disclosures or arguments of "useful in research" or "useful as building blocks of value to the researcher" would not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Rather than setting a de minimus standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (Jolles, 628 F.2d at 1327-28, 206 USPQ at 891); by evidence showing successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally compounds (Cross, 753 F.2d at 1051, 224 USPQ at 748); and by evidence showing in vivo antitumor activity in mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana, 551 F.3d at 1567, 34 USPQ2d at 1442).

The asserted generic utilities for the claimed arrays-for gene expression monitoring and functional analysis-does not satisfy the utility requirement of § 101. Such a use does not provide a specific benefit in currently available form.

It is not questioned that the claimed arrays could be useful for the recited utilities. However, the specification provides no guidance to allow a skilled artisan to use data relating to eukaryotic gene expression and functional analysis in a practical way. The specification provides no guidance regarding what the information derived from a microarray of the invention would mean. Assume, for example, that a fragment was attached to a microarray and the researcher observed that expression of a portion of the gene fragment was increased when a cell

was treated with a particular agent. The specification provides no basis on which a skilled worker would be able to determine whether such a result is meaningful. The specification provides no guidance as to how to interpret the results that might be seen using the claimed microarrays.

In effect, the position is that the claimed arrays are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental result might mean. Such a disclosure does not provide a "specific benefit on currently available form". Rather, the instant case seems analogous to Brenner. In Brenner, the applicant claimed a method of making a compound but disclosed no utility for the compound. 383 U.S. at 529, 148 USPQ at 693. The Court held that a process lacks utility if it produces a product that lacks utility. Id. at 534, 148 USPQ at 695. Here, the applicants claim a product asserted to be useful in gene expression analysis, but the specification does not disclose how to interpret such data. Just as the process claimed in Brenner lacked utility because the specification did not disclose how to use the end-product, the product claims here lack utility because the specification does not disclose how to use the array or any results that would come from it.

The Supreme Court noted that the patent system contemplates a basic quid pro quo: in exchange for the legal right to exclude others from his invention for a period of time, an inventor discloses his invention to the public. See Brenner, 383 U.S. at 534, 148 USPQ at 695. The Brenner Court held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility-a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the applicant has not met his side of the bargain, and has not provided a disclosure sufficient to justify a grant of the right

to exclude others. See id. While a specification need not disclose what is well known in the art, that rule does not excuse an applicant from providing a complete disclosure. See Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): "It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement."

Thus, the burden would be on the artisan using the array to determine a real world utility for the array that is specific and substantial, and the claims are so rejected for lacking a specific and substantial utility.

Claims 61-81 and 93-104 are also rejected under **35 U.S.C. 112, first paragraph**. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68, 69, 72-74, 80 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 68, 68, and 72-74 recite various sources from which the microarray may come. However, this is vague and indefinite as it is unclear as to how the source further limits the microarray or the sequences contained on the array.

Regarding claim 72, the phrase "at least in part" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 80 recites "control probes". However, it is unclear what is meant by "control". Are the probes positive or negative controls and what are they controls for? Hybridiztion? Signal intensity?

Claim 81 recites the limitation "in the eukaryotic genome" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Also regarding claim 81, the phrase "identically contiguous" is unclear. What is the definition of identically contiguous? Does applicant intend for this to mean that the sequences from the intronic sequence are base for base the same as the sequences in an exon from a eukaryotic genome?

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

MARJORIE MORAN
PATENT EXAMINER

January 26, 2004

Lori A. Clow, Ph.D.
Art Unit 1631